ASCENTAGE PHARMA GROUP INTERNATIONAL

亞盛醫藥集團

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6855)

Voluntary Announcement

Ascentage Pharma Received Clearance from U.S. FDA to Initiate Global Registrational Phase 3 Clinical Trial for Olverembatinib in Previously Treated Patients with Chronic Phase Chronic Myeloid Leukemia (CML-CP)

Ascentage Pharma Group International (the "**Company**" or "**Ascentage Pharma**") is pleased to announce that it has received clearance from the U.S. Food and Drug Administration ("**FDA**") to initiate a Phase 3 registrational trial of olverembatinib (HQP1351) in previously treated patients with chronic phase chronic myeloid leukemia (CML-CP), both with and without the T315I mutation. This trial marks the first global Phase 3 registrational trial for olverembatinib cleared by the U.S. FDA.

The trial, titled "A Global Multicenter, Open Label, Randomized, Phase 3 Registrational Study of Olverembatinib (HQP1351) in Patients with Chronic Phase Chronic Myeloid Leukemia (POLARIS-2)" under protocol HQP1351CG301, is a global, multi-center, randomized and controlled registrational phase 3 clinical trial designed to assess the efficacy and safety of olverembatinib for the treatment of patients with CML-CP with and without the T315I mutation. The trial is scheduled to commence during the first half of 2024.

Olverembatinib is Ascentage Pharma's Class 1 innovative drug, and a best-in-class innovative drug globally. As the first and only marketed third generation BCR-ABL inhibitor, olverembatinib has outstanding effects on BCR-ABL and a variety of BCR-ABL mutants (including T315I mutation). In November 2021, olverembatinib was approved in China for the treatment of adult patients with TKI-resistant CML-CP or accelerated-phase CML (CML-AP) harboring the T315I mutation. In January 2023, olverembatinib has been officially included into the China National Reimbursement Drug List. In Novembeer 2023, olverembatinib has been approved by NMPA for Treatment of CML-CP Patients who are Resistant and/or Intolerant to 1st and 2nd Generation TKI Treatment. Recently, olverembatinib was also included in NCCN guideline for the management of CML. Ascentage Pharma is committed to the expansion of commercialization and availability of olverembatinib in the China market and abroad.

By Order of the Board
Ascentage Pharma Group International
Dr. Yang Dajun
Chairman and Executive Director

Suzhou, People's Republic of China, February 14, 2024

As at the date of this announcement, the Board of Directors of the Company comprises Dr. Yang Dajun as Chairman and executive Director, Dr. Wang Shaomeng and Dr. Lu Simon Dazhong as non-executive Directors, and Mr. Ye Changqing, Dr. Yin Zheng, Mr. Ren Wei and Dr. David Sidransky as independent non-executive Directors.

References:

1. O'Brien SG, Guilhot F, Larson R, et al. Imatinib compared with interferon and low-dose cytarabine for newly diagnosed chronic-phase chronic myeloid leukemia. *Engl J Med*. 2003 Mar 13;348(11):994-1004.

2. Jabbour E, Kantarjian H. Chronic myeloid leukemia: 2014 update on diagnosis, monitoring, and management. *Am J Hematol*. 2014 May;89(5):547-56.

3. Larson R, Hochhaus A, Hughes T, et al. Nilotinib vs imatinib in patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase: ENESTnd 3-year follow-up. *Leukemia*. 2012 Oct;26(10):2197-203.